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ABSTRACT

This paper discusses the need for educational researchers to employ a system for protecting human subjects who participate in research and development programs. The ethical obligations of researchers, as well as the Department of Health, Education, and Welfare's policy guidelines, are examined. Following this discussion, the author describes the review procedures used by Research for Better Schools, Inc. (RBS), as one example of a program designed to protect research subjects from possible economic, psychological, or medical risks. In addition, Appendix A contains detailed specifications for informed consent agreements, Appendix B lists areas of concern for the RBS Committee for the Protection of Human Subjects, and Appendix C describes major policy decisions of the RBS Committee. (JG)

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PROTECTION OF HUMAN SUBJECTS IN EDUCATIONAL RESEARCH

by

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Presented by

JoAnn Weinberger
Research for Better Schools, Inc.
Philadelphia, Pennsylvania

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PROTECTION OF HUMAN SUBJECTS IN EDUCATIONAL RESEARCH

Within the maze of activities that contribute to research and development, ethical considerations demand continuous professional attention. Responsible researchers must proceed with respect and concern for the welfare of the subjects who participate in R&D programs.

This paper will focus on:

> the need to establish a system for the protection of human subjects;
>
> a case study describing the operation of a system designed to protect human subjects; and
>
> a summary of the decisions made within this system for the protection of human subjects in educational research.

Every researcher has an obligation to protect subjects participating in research experiments or development programs. In the case of educational research, children as subjects present ethical considerations different than those presented by adult subjects. Children have less knowledge and experience; therefore, they are less able to evaluate what participation in research may mean. Thus, the investigator and the institution must be responsible for establishing and maintaining ethical practices.

Department of Health, Education and Welfare policy requires that prospective grantees provide assurances to protect human subjects involved in research. Guidelines for the establishment of policy and procedures are provided by DHEW in a National Institute of Health/DHEW document entitled "The Institutional Guide to DHEW Policy and Protection of Human Subjects." As part of the procedures, each institution provides a statement of compliance assuring DHEW that it will establish and maintain a competent committee that will analyze each planned activity to determine that:

-- The rights and welfare of subjects are adequately protected.

-- The risks to subjects are outweighed by potential benefits.

-- The informed consent of subjects will be obtained by methods that are adequate and appropriate.

According to DHEW guidelines, an individual is considered to be "at risk" if s/he may be exposed to the possibility of harm -- physical, psychological or other -- as a consequence of any activity which goes beyond the application of those established and accepted methods necessary to meet his needs. The more obvious examples of risk include the requirement of strenuous exercise or subjections to deceit, public embarrassment and humiliation. Procedures which could not be condoned might involve discomfort, anxiety, harrassment, invasion of privacy or any action that constitutes a threat to the subject's dignity through the imposition of demeaning or dehumanizing procedures.

Informed consent is the agreement obtained from a subject, or from his authorized representative, to participate in a particular research activity. It serves to respect the individual's autonomy and his right to make choices about his own life by providing a subject with information about the experiment. Securing informed consent may provide secondary benefits by encouraging the investigator to question the value of the proposed project and the adequacy of measures to protect subjects. Furthermore, informed consent may serve to increase society's awareness about human research. Detailed specifications for informed consent may be found in Appendix A.

Current policy calls for a self-regulatory system in which a decentralized institutional review panel is charged with the responsibility of seeing that the investigator adheres to the three broad guidelines stated above. The review process and the decisions rendered must be fully documented. Furthermore, committee records must be available for audit at any time.

However, recent experience with human experimentation in various disciplines has prompted renewed co[illegible]n among the professions and the public that the present regulations regarding the research process are unsatisfactory. Some critics call for increased government controls, more detailed codes of

ethics, more powerful professional review committees or more active participation of non-scientists in the research carried out with human subjects. Others fear that involvement of outsiders or more stringent controls will prohibit scientific progress and creativity.

More specifically, current proposed changes in NIH/DHEW policy require:

1. Inter-disciplinary committees that are composed of some members from outside the organization sponsoring the proposal.
2. Review and approval of all proposals involving human subjects by a Committee before submission to DHEW for funding. To comply with this, informed consent procedures would have to be followed before the investigator was assured funding.
3. Informed consent of parents of subject children and the consent of the children themselves if they are seven years of age or older.

These proposed measures highlight the tension which exists between current self-determination and the delegation of authority to experts. Questions which remain unanswered include: To whom do you delegate authority? Who are the experts? What are their distinctive qualities? What risks are and should be acceptable? What values do we seek to maximize by accepting or rejecting certain kinds of risks?

An example of the review procedures used by an educational research and development institution, Research for Better Schools, Inc. (RBS) provides an insightful case study and a model of the processes used to protect human subjects. RBS is committed to the development, testing and dissemination of programs that individualize and humanize instruction from early childhood through later life. To accomplish this mission, it is involved in developing products that will optimize opportunities for intellectual growth as well as promote self-reliance, responsibility and responsiveness to changing social and technological environments. For this type of institution, the ethical considerations, some

of which are unique to education, are constantly highlighted to assure that the rights and welfare of the subjects involved in research and development activities are adequately protected.

RBS receives the majority of its funding from the Department of Health, Education and Welfare through the Office of Education (1966-1972) and the National Institute of Education (1973-). Therefore, in 1972, RBS prepared a formal policy and procedures, signed a Statement of Compliance for General Institutional Assurance, and submitted them to the Institutional Relations Branch, Division of Research of the National Institutes of Health. To fulfill its obligation, RBS established a committee competent to review projects and activities that involve human subjects. In appointing the members of the Committee, the Executive Director stipulated two conditions: (1) members of the RBS staff would be excluded and (2) representatives from different disciplines would be included. Conflict of interest would not be a problem since committee members would be non-RBS staff. Furthermore, a more detailed examination of plans and proposals would occur if outsiders were brought in as consultants for ethical review only.

The second condition, an inter-disciplinary committee in which each member could bring his expertise to the inter-ethical analysis of activities, was met by choosing a lawyer, a school principal, a psychologist, an educational R&D specialist and a member of the RBS Board of Directors to serve on the review committee.

Committee review of curriculum and evaluation designs and materials is conducted three times a year with objectivity and in a manner to ensure the exercise of independent judgment of the members. Materials to be submitted to the Committee are determined by the principal investigator and a member of the RBS staff who serves as a committee liaison. The information provided to the Committee usually consists of a general description of the project, examples of curriculum materials, plans for collecting and using data, all

evaluation instruments, and procedures for protecting confidentiality of subjects. Submitted with the materials is the following form showing the investigator's assessment of the risk involved:

> I have read the attached instructions concerning human experimentation and herewith submit to the Committee all the information it needs to judge the risks within this program.
>
> 1. Having read the preceding statement defining risk, in my opinion, the risk for the subjects in the proposed project is:
>
> _____minimal
>
> _____some
>
> _____acceptable and within expected bounds
>
> _____acceptable but exceeding expected bounds
>
> _____not acceptable.
>
> 2. I am attaching information which includes:
>
> a. provisions to be used in guarding the rights and welfare of the human subjects in this research
>
> b. a description of the methods to be employed for securing Informed Consent of the subjects, where necessary, with copies of the form and explanation to be used
>
> c. a description of the risks to the subjects and the potential benefits of this research to the subjects and to the public.
>
> Should any change in methods become advisable, I will bring this to the attention of the Review Committee before changes are initiated."

The Committee prepared this form after concluding that all research and development activities have at least a minimal degree of risk, and that this should be recognized by all investigators. The minimal degree of risk is not to be equated with DHEW defined risk.

In attendance at the Committee reviews are the five appointed members (three are required for a quorum); the Executive Director of RBS; his designee who is the liaison between the RBS investigators, the Committee and DHEW, and the Director of Education. The liaison is responsible for the documentation and minutes of Committee reviews. At its first meeting, the Committee chose not to elect a chairman; instead, all members have equal authority. If a

member has a concern, then all members must interact until the question is resolved.

Areas investigated by the Committee include the confidentiality of subjects and the collection, inter-connection and utilization of data in the cognitive and affective areas, both at RBS and on site (the school). The Committee's review of proposals includes questions such as:[1]

- What is the degree of risk?
- Is the risk unusual?
- Is the risk extended?
- How many subjects are at risk?
- Is the risk worth the gain?
- What is the type of risk? one of causing anxiety? invasion of privacy? causing discomfort? threat to dignity or self-image? economic loss?

Since this Committee was established in February of 1972, major policy decisions have been made. These include, as examples:[2]

1. The Committee believes that persons participating in educational programs either as students or staff members may be subject to at least three distinguishable types of risks: economic, psychological and medical. The Committee is concerned about all three types of risks, inasmuch as the research and development programs operated by RBS may entail all three types; however, economic and psychological risks are particularly likely, the first during program development and the second during program evaluation.

   The particular form of economic risk to which a participant in an educational program is most likely to be subject is the possible waste of his or her time. To combat this particular risk, the following should be established by the RBS staff in planning research and development activities:

   a) There is an expectation of potential benefit in terms of students' learning faster and better as a result of the research or development activity.

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[1] The complete set of questions asked whenever the collection and/or inter-connection of data are involved may be found in Appendix B.

[2] A complete listing of Committee policy decisions and specific examples of implementation may be found in Appendix C.

b) The developmental cycle provides for short unit sequences tested and then modified, and the sequences being as short as feasible to minimize possible time loss for the students.

c) The number of students involved is as small as can reasonably be arranged consistent with the objectives of the research or development activity. As the risk is reduced, the number of students involved can be increased.

2. Community acceptance of a purpose or a procedure as being a normal part of an educational treatment can be used as one criterion for determining the acceptability of a purpose or procedure.

3. The identification of subjects, schools, and the school districts should not be readily reconstructable and should be reconstructable, of course, only by authorized personnel.

In fulfilling its obligations, the Committee has never completely rejected proposed activities; however, clarification and/or alterations in procedures and instruments have been mandated. Examples of Committee mandates have included:

1. Changing in-house procedures for storing of raw data to insure confidentiality.
2. Revising forms for informed consent to add specificity.
3. Rewriting particular items in evaluation instruments before the questionnaires could be administered.

Committee decisions, along with their rationale, are recorded in the Minutes of the Committee and given to the principal investigators.

An additional benefit derived from the Committee is its ongoing constructive suggestions. Going beyond its assigned responsibility, the Committee uses its technical expertise to add external, varied input to program planning and the development of evaluation instruments.

Thus, the Review Committee for the Protection of Human Subjects at Research for Better Schools provides a system assuring that the rights and welfare of human subjects are protected. The value of this Committee and its commitment to the individual make a unique contribution to educational research and development.

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APPENDIX A

INFORMED CONSENT

INFORMED CONSENT

Informed Consent is the agreement obtained from a subject, or from his authorized representative, to participate in an activity. DHEW defines basic elements of Informed Consent in the six statements which follow. However, in some instances these may be modified or eliminated - see Item C. next page.

1. A fair explanation of the procedures to be followed, including an identification of those which are experimental;

2. A description of any attendant discomforts and risks;

3. A description of any benefits to be expected;

4. A disclosure of any appropriate alternative procedures that would be advantageous to the subject;

5. An offer to answer any inquiries concerning the procedures; and

6. An instruction that the subject is free to withdraw his consent and to discontinue particpation in the project or activity at any time.

In addition, the agreement, written or oral, entered into by the subject, should include no exculpatory language through which the subject is made to waive, or appear to waive, any of his legal rights, or to release the institution or its agents from liability or negligence. Informed Consent must be documented. The documentation will follow one of the following three forms:

A. Provision of a written consent document embodying all of the basic elements of Informed Consent. This form is to be signed by the subject or his authorized representative. A sample of the form as approved by the Committee is to be retained in its records. Completed forms are to be retained by the Program Director.

B. Provision of a "short" form written consent document indicating that the basic elements of Informed Consent have been presented orally to the subject. Written summaries of what is to be said to the subject are to be approved by the Committee. The "short" form is to be signed by the subject or his authorized representative and an auditor-witness to the oral presentation and to the subject's or his authorized representative's signature. A copy of the approved summary, annotated to show any additions, is to be signed by the persons obtaining the consent on behalf of the institution and by the auditor-witness. Sample copies of the consent form and of the summaries as approved by the Committee are to be retained in its records. Completed forms are to be retained by the Program Director.

C. Modification of either of the above two primary procedures must be approved by the Committee in the minutes signed by the Chairman. Granting of permission to use modified procedures imposes additional responsibility upon the Review Committee and the institution to establish that the risk to any subject is minimum, that use of either of the primary procedures for obtaining Informed Consent would surely invalidate objects of considerable immediate importance, and that any reasonable alternative means for attaining these objects would be less advantageous to the subject.

APPENDIX B

AREAS OF CONCERN

Collecting Data

Inter-Connecting Data

COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS

AREAS OF CONCERN

ON SITE		RBS
Collecting Data: Cognitive	)	What is the type of risk: cause of anxiety? invasion of privacy? cause of discomfort? threat to dignity of self-image? economic loss?
	)	What is the degree of risk?
	)	Is the risk unusual?
	)	Is the risk extended?
Affective	)	How many subjects are at risk?
	)	Is the risk worth the gain?
	)	Who is the beneficiary: the individual? society?
	)	If risk is involved, how difficult is it to remove the risk?
	)	Will the subject or his representative give informed consent?
	)	

AREA OF CONCERN (Continued)

	ON SITE	RBS
Inter-connecting Data:*		
Cognitive	)	What is the type of risk: cause of anxiety? invasion of privacy? cause of discomfort? threat to dignity or self-image? economic loss?
	)	Is the risk unusual?
	)	Is the risk extended?
	)	How many subjects are at risk?
	)	Is the risk worth the gain?
	)	What steps would have to be taken to inter-connect data?
	)	Are the data which can be inter-connected sensitive?
	)	Who is the beneficiary: the individual? society?
	)	If risk is involved, how difficult is it to remove the risk?
Affective	)	
	)	
	)	
	)	
	)	
	)	
	)	
	)	
	)	
	)	
	)	

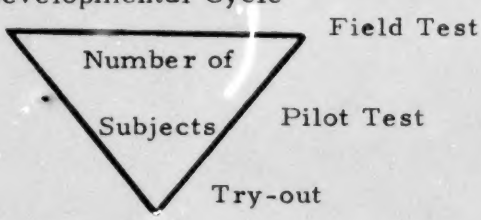
* The concern in the area of inter-connecting data is the linking of different records on the same individual. Developing a large bank of knowledge on the students in one school without precise reasons given will be questioned by the Committee.

APPENDIX C

COMMITTEE POLICY DECISIONS

Since this Committee was established in February of 1972, major policy decisions have been made. These include:

Committee Policy Decisions	Specific Example of Implementation
1. The Committee believes that persons participating in educational programs either as students or staff members may be subject to at least three distinguishable types of risks: economic, psychological and medical. The Committee is concerned about all three types of risks, inasmuch as the research and development programs operated by RBS may entail all three types; however, economic and psychological risks are particularly likely, the first during program development and the second during program evaluation. The particular form of economic risk to which a participant in an educational program is most likely to be subject is the possible waste of his or her time. To combat this particular risk, the following should be established by the RBS staff in planning research and development activities: a) There is an expectation of potential benefit in terms of students' learning faster and better as a result of the research or development activity. b) The developmental cycle provides for short unit sequences tested and then modified, with the sequences being as short as feasible to minimize possible time loss for the students.	In terms of curriculum, the developmental cycle utilized was examined in terms of the possible risks: a) the pupil would waste time in school, and b) the pupil would not learn the particular subject matter. However, due to the developmental cycle utilizing short instructional sequences, the attendant risks were considered minimal since the student could recover in a reasonable amount of time. The potential benefits are the possibility of learning faster and better.

Committee Policy Decisions	Specific Example of Implementation
c) The number of students involved is as small as can reasonably be arranged consistent with the objectives of the research or development activity. As the risk is reduced, the number of students involved can be increased. This may be represented by an inverted pyramid: Developmental Cycle  	
2. Community acceptance of a purpose or a procedure as being a normal part of an educational treatment can be used as one criterion for determining the acceptability of a purpose or procedure.	Achievement and affective testing are acceptable evaluation procedures.
3. The identification of subjects, schools, and the school districts should not be readily reconstructable and should be reconstructable, of course, only by authorized personnel.	The Committee recommends that names and coded data be kept in separate locations. For example, class lists and data should be kept in separate file cabinets. The computer should not be able to associate pupil name with research data at a Computer Center. Research data are defined as information not reported by individual names.

Committee Policy Decisions	Specific Example of Implementation
4. Since there is some risk to the body of children attending a school if the results of an educational treatment are negative and publicly reported, information about the results of educational programs should be reported only to the schools in which the information originates. Within RBS, schools should be assigned numbers for data processing.	All schools have codes for data processing. Information, identified by school name, is only reported to that individual school. Any comparative reports use schools codes.
5. Data should not be given to a school to augment the permanent record of a student unless it would be of specific help to local school personnel. The Committee wants to be kept informed about all the types of information being returned to schools about individual students.	In one project, the information being returned to the student's home school was reviewed and approved since the pupil record is not being augmented. The only test results being returned are on an achievement test used by that school district.
6. Whenever it can be accomplished with reasonable economy and convenience, pupil names should be replaced by codes before data enters RBS. These codes should be assigned at the field sites with no master lists kept at RBS. Using this procedure, no information at RBS could be associated with the individual supplying it and the subjects would be protected.	In one project, pupil codes are justified based on administrative feasibility - there are fewer classes and pupils. However, a master list is kept at RBS.
7. The RBS staff should not be held responsible for arrangements adopted by the school to use intelligence and standarized achievement test data that RBS supplies to a school in lieu of regular school district testing program.	RBS cannot be held responsible for what the school does with the information, either by insisting that they meet certain security procedures or by monitoring so that the schools do indeed meet those procedures. The schools receive no more data than they would have received from their central office.

Committee Policy Decisions.	Specific Example of Implementation
8. To reduce the risk that a school will misuse research or development data supplied to it by RBS, the school should be required to seek permission of RBS before releasing data which RBS has supplied.	All schools receiving data from RBS are informed of this decision.
9. Parent questionnaires should be designed to avoid questions which would appear to suggest to parents that they take certain actions with respect to their children when such actions, if taken, might turn out to be counter-productive to learning.	RBS should not develop questionnaires which imply values, and hence suggest, by implication, action. In this regard, concern should be given to length, specificity of questions, avoidance of generalities, etc.
10. In collecting demographic data, the RBS staff should not ask for information that is personally evaluative. If the information is not a matter of objective fact but involves a judgment by the respondent, asking the question may be personally damaging.	In one project, the procedures used in collecting initial screening data were changed so as not to include asking the students to request letters of recommendation.
11. Religious preference of subjects should not be asked.	The Committee was assured that religious preference was not to be completed even though there was a place for it on the Personal Observation Inventory used by one project.

Committee Policy Decisions	Specific Example of Implementation
12. There is a question of risk to teachers when the responses of students about the instructional process are given to the school principal or to the district superintendent. The criteria for considering the extent of risk in this situation are: a) It is a generally acceptable procedure for responses to such items to be presented to principals and other administrators. b) Benefits to the students outweigh the risks to the teacher as an object of investigation. c) It is the responsibility of the RBS staff to help administrators interpret the data since the teacher is one element in implementing curriculum but other elements can also affect student learning. d) When the teacher sees the instrument before administering it, s/he has given de facto informed consent.	Questionnaires which include item(s) asking for the student's response about his teacher(s) are acceptable evaluation measures.
13. The policy of RBS is to inform and obtain a written consent on the use of a curriculum and/or teaching procedure in any formalized program which poses unusual and extended risk to the individual or which provides material intended for purposes other than program evaluation and revision.	Informed Consent signed by parents of entering students in the Academy for Career Education was required since the creation of a new school may provide for unusual curriculum and teaching procedures.

Committee Policy Decisions	Specific Example of Implementation
14. When audio visual records of an educational activity are made for research or development purposes, a release form should consit of a full disclosure of the possibility that the audio visual materials may be used for purposes other than for evaluation and revision. The inclusion of full information about these possibilities in the release form is necessary so that the persons granting the release may realize that they are waiving their right to privacy and any claims of economic benefit from the subsequent sale or use of the audio-visual materials.	For one program, the consent form written to incorporate the Committee's recommendations.